Table 1. Baseline Patient and Disease Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRAF V600E Mutation Status</td>
<td>45</td>
<td>13 (29.2)</td>
<td>9.0 (19.0)</td>
<td>13 (29.2)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>45</td>
<td>55.0 (14.0)</td>
<td>13.4 (38.7)</td>
<td></td>
</tr>
<tr>
<td>ECOG Performance Status</td>
<td>45</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td></td>
</tr>
<tr>
<td>Number of Lesions</td>
<td>45</td>
<td>2 (1.0)</td>
<td>2.0 (4.0)</td>
<td></td>
</tr>
<tr>
<td>Clinical Tumor Size (cm)</td>
<td>45</td>
<td>4.0 (6.4)</td>
<td>3.0 (6.3)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Safety Summary

<table>
<thead>
<tr>
<th>Event</th>
<th>n</th>
<th>Grade</th>
<th>Any Event</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
<th>Grade 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>All events</td>
<td>110</td>
<td>95 (86.4)</td>
<td>14 (12.7)</td>
<td>1 (0.9)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>110</td>
<td>84 (76.4)</td>
<td>16 (14.5)</td>
<td>2 (1.8)</td>
<td>1 (0.9)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Asthenia</td>
<td>110</td>
<td>85 (77.3)</td>
<td>13 (11.8)</td>
<td>3 (2.7)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Table 3. Best Overall Response for ITT Population by RECIST v1.1

<table>
<thead>
<tr>
<th>Response</th>
<th>n</th>
<th>Complete Response</th>
<th>Partial Response</th>
<th>Stable Disease</th>
<th>Progressive Disease</th>
<th>Not Assessed</th>
<th>ORR</th>
<th>DCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>14 (24.4)</td>
<td>11 (21.3)</td>
<td>22 (39.1)</td>
<td>10 (26.8)</td>
<td>0 (0.0)</td>
<td>25 (54.4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4. Objective Response by BFAST Expression Status

<table>
<thead>
<tr>
<th>BFAST Score</th>
<th>n</th>
<th>Complete Response</th>
<th>Partial Response</th>
<th>Stable Disease</th>
<th>Progressive Disease</th>
<th>Not Assessed</th>
<th>ORR</th>
<th>DCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 0.000</td>
<td>25</td>
<td>1 (4.0)</td>
<td>4 (16.0)</td>
<td>13 (52.0)</td>
<td>7 (28.0)</td>
<td>0 (0.0)</td>
<td>12 (48.0)</td>
<td></td>
</tr>
<tr>
<td>&lt; 0.000</td>
<td>20</td>
<td>3 (15.0)</td>
<td>8 (40.0)</td>
<td>4 (20.0)</td>
<td>5 (25.0)</td>
<td>0 (0.0)</td>
<td>17 (85.0)</td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Percent Change From Baseline in Lesion(s)

<table>
<thead>
<tr>
<th>Tumor</th>
<th>ORR</th>
<th>DCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Response</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

Figure 5. Percent Change From Baseline in Lesion(s)

Figure 6. Increase in Infiltration of Immune Cells Correlated with Clinical Response

Figure 7. Upregulation of Immune Related Signature Correlates with Clinical Response

Figure 8. Increased Density of Immune Cells in SD-101 Treated Lesions Correlates with an Overall Decrease in Tumor Burden

CONCLUSIONS

1. SD-101 is able to boost NK cell cytotoxic activity and induce recruitment of T cells. In addition, SD-101 is a synthetic class I Tumor antigens that migrate to the lymph node to take up and process antigens.

2. Clinical activity was observed in a phase 1b/2 open label, multicenter, study of the combination of SD-101 and an anti-PD-L1 therapy.

3. Safety was consistent with what was previously observed in prior studies of SD-101.

METHODS

1. Methods and materials

2. Study Design

3. Study Population

4. Study sites

5. Treatment Schedule

6. Efficacy

7. Safety

8. Analysis

9. Results

10. Discussion

REFERENCES


